

Food Safety and Inspection Service Washington, D.C. 20250

JUN 18 2004

Dr. Osmo Maki-Petays Head of Meat Hygiene Unit National Veterinary & Food Research Institute Hameentie 57 Fin-00231 Helsinki, Finland

Dear Dr. Maki-Petays:

The Food Safety and Inspection Service completed an on-site audit of Finland's meat inspection system. The audit was conducted from January 12 through 29, 2004. Comments from Finland have been included in the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White, Director

International Equivalence Staff Office of International Affairs

Enclosure

cc:

Country File

Alejandro Checchi-Lang, Director, Directorate E, European Commission, Brussels Lana Bennett, Minister Counselor, American Embassy, Stockholm Hannele Tikkanen, Agric. Counselor, Embassy of Finland Norval Francis, Minister-Counselor, US Mission to the EU in Brussels Tony Van der haegen, EU Mission to the US, Washington, DC James Dever, FAS Area Officer Dave Young, FAS Amy Winton, State Department Linda Swacina, Deputy Administrator, FSIS Karen Stuck, Assistant Administrator, OIA, FSIS Donald Smart, Director, Program Review, OPEER, FSIS Clark Danford, Director, IEPS, OIA, FSIS Sally White, Director, IES, OIA, FSIS Mary Stanley, Director, IID, OIA, FSIS Shannon McMurtrey, IES, OIA, FSIS Jack Mowbray, IES, OIA, FSIS

FINAL

MAY 28 2004

FINAL REPORT OF AN AUDIT CARRIED OUT IN FINLAND COVERING FINLAND'S MEAT PRODUCT INSPECTION SYSTEM

January 12 through January 29, 2004

Food Safety and Inspection Service United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA Central Competent Authority

E. coli Escherichia coli

FSIS Food Safety and Inspection Service

PR/HACCP Pathogen Reduction/Hazard Analysis and Critical Control Points

Systems

NFA National Food Agency

NOID Notice of Intent to Delist

Salmonella Salmonella species

SSOP Sanitation Standard Operating Procedure(s)

VEA European Community (EC)/United States Veterinary Equivalence

Agreement

1. INTRODUCTION

The audit took place in Finland from January 12 through January 29, 2004.

An opening meeting was held on January 12, 2004, in Helsinki with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit, the auditors' itinerary, and requested additional information needed to complete the audit of Finland's meat inspection system.

The auditors were accompanied during the entire audit by representatives from the CCA, the National Food Agency (NFA).

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, one provincial inspection office, one government-owned residue laboratory and one private microbiology laboratory performing analytical testing on United States-eligible product, three slaughter and processing establishments, one slaughter establishment, and one cold storage facility.

Competent Authority Visits		Comments	
Competent Authority	Competent Authority Central		Helsinki
	Provincial		
Local		4	Establishment level
Laboratories			
Meat Slaughter and Processing Establishments			
Cold Storage Facilities			

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to five establishments: three slaughter and cutting establishments, one slaughter establishment and one cold storage facility. The third part involved visits to one government-owned and -operated residue laboratory and one private microbiology laboratory. The National Veterinary and Food Research Institute laboratory in Helsinki and *HK Ruokatalo Oyj Laboratory* in Forssa were conducting, respectively, analyses of field samples for residues and microbiology for the establishments certified to export product to the United States.

Program effectiveness determinations of Finland's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs, (4) residue controls, and (5) enforcement controls. Finland's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditors evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditors also assessed how inspection services are carried out by Finland and also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

During the opening meeting, the auditors explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community (EC)/United States Veterinary Equivalence Agreement (VEA), the FSIS auditors would audit the meat inspection system against EC Directive 64/433/EEC of June 1964; EC Directive 96/22/EC of April 1996; and EC Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditors would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification, and FSIS requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella* species.

Third, the auditors would audit against any equivalence determinations that have been made by FSIS for Finland under provisions of the Sanitary/Phytosanitary Agreement. One alternate procedure has been recognized as equivalent: testing for generic *E. coli* is performed by the CCA and testing for *Salmonella* species is performed by the establishment under CCA supervision.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to End), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following EC Directives was also assessed:

• EC Directive 64/433/EEC, of June 1964, entitled "Health Problems Affecting Intra-Community Trade in Fresh Meat"

- EC Directive 96/23/EC, of 29 April 1996, entitled "Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products"
- EC Directive 96/22/EC, of 29 April 1996, entitled "Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of β-agonists"

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address: http://199.140.65.44/regulations & policies/Foreign Audit Reports/index.asp

The last two audits of Finland's inspection system have shown several problems. During the September 2002 audit of Finland's inspection system, the following deficiencies were identified:

- In one establishment, pre-operational cleaning of some product-contact surfaces was inadequate.
- In one establishment, maintenance of over-product structures had been seriously neglected.
- In one establishment, light intensities at some post-mortem inspection stations did not meet either E.C. or U.S. requirements.
- In two establishments, several stainless combo bins, which were being used for exposed product, were cracked and in need of repair.
- In one establishment, several white plastic containers, intended for edible product, were found to be used for other purposes without being labeled appropriately.
- In one establishment, the in-plant NFA personnel and the slaughter foreman were usually not notified when contamination with ingesta or feces was found at the pre-boning trim station.
- In one establishment, a review of the monitoring records for the Critical Control Point (CCP) for absence of visible contamination with ingesta/feces showed that the critical limit had been exceeded on six of the past seventeen days, and up to three times per day on several of those days.
- In one establishment, the written preventive measures required when visible contamination with ingesta or feces is found after the CCP for absence of visible contamination was not being followed.
- In one of the four slaughter establishments, testing for generic *E. coli* was not conducted properly.

- In all establishments, establishment personnel were taking samples for generic *E. coli*; whereas this should have been done by the government officials.
- In one establishment, the NFA personnel were taking samples for *Salmonella* species, whereas the establishment employee should have taken the samples.
- In the residue laboratory, there were no written corrective actions to be followed in the event that an analyst's performance did not meet expectations.

All of the deficiencies identified in September 2002 had been corrected by the next audit in March 2003.

In the FSIS audit of March 2003, the following deficiencies were identified:

- In two establishments, maintenance and cleaning of over-product structures had been neglected to varying degrees in several production areas, although no direct product contamination resulting from the neglect was observed during the audit.
- In one establishment, general housekeeping in the chemical storage area had been neglected.
- In one establishment, cross-contamination was observed between a carcass that was railed out and another carcass that had fallen on the floor.

6. MAIN FINDINGS

6.1 Legislation

The auditors were informed that the relevant EC Directives, determined to be equivalent under the VEA, had been transposed into Finland's legislation.

6.2 Government Oversight

The NFA has the organizational structure and staffing to ensure uniform implementation of U.S. requirements. It is responsible for directing, planning, and developing food control in Finland and for exercising enforcement over the food inspection system. Activities cover the control of all foodstuffs from farm to table. The NFA guides the municipal food control authorities, provincial governments, and the National Board of Customs, which perform the practical control. The NFA is subordinate to the Ministry of Agriculture and Forestry.

6.2.1 CCA Control Systems

The NFA is divided into five units: the Meat and Fish Hygiene Unit, the Milk and Egg Hygiene Unit, the Health Protection Unit, the Food Control Unit, and the Administrative Unit. The Meat and Fish Hygiene Unit is responsible for guidance and direction tasks under the relevant hygiene acts. This unit is also responsible for some tasks under the Act

on the Implementation of the Common Agricultural Policy. The unit develops the uniformity and efficiency of food control in its own area. The meat inspection personnel (approximately 100) belong to this Unit. The NFA cooperates closely with the National Veterinary and Food Research Institute and the Plant Production Inspection Centre.

The Ministry of Agriculture and Forestry transposes all relevant European Union legislation into Finnish law.

Mainland Finland is divided into five Provinces. Three of the establishments certified for U.S.-export are located in the Province of Western Finland and two in the Province of Southern Finland. This audit included a visit to the Provincial Veterinary Office in the Province of Southern Finland.

Guidelines have been developed by a crisis working group in the NFA to be implemented in the case any terrorism activities are suspected.

6.2.2 Ultimate Control And Supervision

The tasks of the NFA include meat inspection and control in slaughterhouses and other establishments, approval of the slaughterhouses and establishments in connection with slaughterhouses, national testing programs for residues and for *Salmonella* species in meat, and controls for meat exports outside the European Union. The in-plant inspection personnel are supervised both by the NFA Senior Veterinary Officers (stationed in Helsinki) and by the Provincial Veterinary Officers (PVOs), who perform the monthly internal reviews of the establishments certified as eligible to produce products for U.S. export. Under the current system, all issues that may arise regarding animal health and welfare are expected to be channeled through the PVOs. The PVOs carry the responsibility to evaluate and report on the performance of the in-plant inspection personnel and export procedures. The PVOs, in turn, are also supervised by the NFA Senior Veterinary Officers in Helsinki.

The PVOs discuss their routine evaluation of the performances of the in-plant inspection personnel during the internal reviews. If they have any concerns, they discuss this with their supervisors after the audit is completed.

Nationally developed inspection forms are in use in all establishments for supervision of establishment compliance. A guideline of written instructions for supervision of establishments eligible for U.S. export, including evaluating PR/HACCP programs and compliance with other FSIS requirements has been developed and implemented.

The EC's regulations regarding movement, identification, and traceability of animals are enforced in Finland.

The national residue testing program is jointly developed, implemented, and applied by (1) the NFA, (2) the National Veterinary and Food Research Institute, and (3) the Ministry of Agriculture and Forestry.

6.2.3 Assignment of Competent, Qualified Inspectors

Veterinarians take courses in meat inspection in the curriculum of their formal education. After graduation, they take further special courses in meat inspection, including four weeks of practical training. They must then pass specific examinations before being qualified to work in establishments. Non-veterinary "auxiliaries" have courses involving 200 hours of practical training on slaughter line and 400 hours of theoretical class work, after which they must also pass specific examination before being qualified to work in export meat establishments.

In-plant inspection personnel, their supervisors (the Provincial Veterinarians), and headquarters officials have participated in additional HACCP training.

No part-time or full-time government employees are allowed to perform private, establishment-paid tasks at an establishment in which they perform official duties. Private-practicing veterinarians may be hired as temporary or part-time government employees in establishments certified for U.S. export.

The NFA charges the establishments monthly for inspection services, according to the applicable European Union Directive, which has been transposed into Finnish legislation, and pays the field inspection personnel directly.

6.2.4. Authority and Responsibility to Enforce the Laws

The NFA has the authority and the responsibility to enforce U.S. and E.C. requirements.

6.2.5. Adequate Administrative and Technical Support

The NFA has adequate administrative and technical support to operate Finland's inspection system and has the resources and ability to support a third-party audit. The NFA is responsible for hiring veterinarians and other inspection personnel and determines the allocation of personnel to the establishments.

6.3 Headquarters Audit

The auditors conducted a review of inspection system documents at the headquarters, provincial and in-plant inspection offices at the audited establishments. The records reviews focused primarily on food safety hazards and included the following:

- Internal review reports,
- Supervisory visits to establishments that were certified to export to the U.S.,
- Training records for inspectors and laboratory personnel.
- Animal disease status.
- Supervisory visits to U.S. certified establishments,
- Label approval records,
- New laws and implementation documents such as regulations, notices, directives and guidelines,

- Official communications with field personnel, both in-plant and supervisory, in U.S. certified establishments.
- Sampling and laboratory analyses for residues.
- Sanitation, and slaughter inspection procedures and standards,
- Species verification policy,
- Export product inspection and control including export certificates, and
- Enforcement actions.

No concerns arose as a result of the examination of these documents.

6.3.1. Audits of Regional and Local Inspection Sites

The provincial inspection office in Helsinki was audited on January 26, 2004, to gain insight into the oversight of establishment-level inspection controls. No concerns arose as a result of this audit.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited three slaughter and processing establishments, one slaughter establishment, and one cold storage facility. None of the five establishments was delisted by Finland's inspection service as a result of failure to meet FSIS requirements. One establishment received a Notice of Intent to Delist (NOID) from the NFA because of SSOP implementation deficiencies. This establishment may retain its certification for export to the United States provided that the management corrects all deficiencies noted during the audit within 30 days of the date the establishment was audited, or it is to be delisted by the NFA.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to United States requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, and intra-laboratory check sample and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check sample programs. If private laboratories are used to test United States samples, the auditors evaluate compliance with the criteria established for the use of private laboratories under the FSIS HACCP/PR requirements.

The following laboratories were audited:

The government-owned and -operated National Veterinary and Food Research Institute laboratory in Helsinki is the reference laboratory for residue testing.

The private *HK Ruokatalo Oyj* Laboratory in Forssa conducts analyses of field samples for microbiology for the establishments certified to export product to the U.S.

The findings in these laboratories will be discussed in Section 11.3 (Testing for generic *E. coli*), 12 (RESIDUE CONTROLS), and 13.2 (Testing for *Salmonella* species) of this report.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditors focused on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditors reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Finland's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, and except as noted below, Finland's inspection system had controls in place for light, ventilation, plumbing and sewage, water supply, dressing rooms/lavatories, equipment and utensils, sanitary operations, employee hygiene, and condemned product control.

- In one establishment, containers designated for edible product were used for inedible product (416.3) (EC Dir. 64/433)
- In two establishments, product residues were observed on over-product structures (416.2b) (EC Dir. 64/433).
- In one establishment, NFA personnel were unable to interpret the reports from the pest control contractor (416.2a) (EC Dir. 64/433).
- In one establishment, condensation was noted on a refrigeration unit in one cooler (416.2d) (EC Dir. 64/433).
- In one establishment, a roll of plastic for edible product was contacting the floor and plastic for packaging was stored in a container designated for inedible materials (416.4a) (EC Dir. 64/433).

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in all four establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies in the implementation of SSOP.

- In one establishment, fat and meat particles were observed on white tubs that were ready for use for edible product (9 CFR 416.13).
- In one establishment, an unclean carcass hoist hook was contacting edible product (9 CFR 416.15).
- In three establishments, the SSOP records did not include adequate descriptions of deficiencies found and corrective actions taken (9 CFR 416.16).

9.2 EC Directive 64/433

In two establishments, the provisions of EC Directive 64/433 were effectively implemented. In the other three establishments, deficiencies were identified. The specific deficiencies are noted in the attached individual establishment reports.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors reviewed was Animal Disease Controls. These include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditors determined that Finland's inspection system had adequate controls in place. No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditors reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem dispositions; humane handling and humane slaughter; post-mortem inspection procedures and dispositions; ingredients identification; control of restricted ingredients, formulations, processing schedules, equipment, and records; and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were identified regarding humane handling or humane slaughter.

11.2 HACCP Implementation

- In two establishments, calibration of the equipment for monitoring critical limits was not clearly defined in the written HACCP plan (9 CFR 417.4).
- In one establishment, the written descriptions of monitoring and verification procedures were not clear. Both were performed, but the records did not reflect the correct terminology (9 CFR 417.4).

11.3 Testing for Generic E. coli

No deficiencies were identified regarding the testing programs for generic E. coli.

11.4 Testing for Listeria monocytogenes

None of the five establishments was producing ready-to-eat products for export to the United States. Accordingly, FSIS requirements for testing for *Listeria monocytogenes* did not apply.

11.4 EC Directive 64/433

In all five establishments, the provisions of EC Directive 64/433 regarding humane handling and humane slaughter were effectively implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditors reviewed was Residue Controls.

The government-owned and -operated National Veterinary and Food Research Institute laboratory in Helsinki was audited. The following observation was made:

• Some recoveries for sulfonamides were as low as 50%. FSIS expects a minimum of 70% recovery for sulfonamides.

12.1 FSIS Requirements

At the time of this audit, four slaughter establishments and one cold-storage facility were certified for U.S. export.

12.2 EC Directive 96/22

In the National Veterinary and Food Research Institute laboratory in Helsinki, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the National Veterinary and Food Research Institute laboratory in Helsinki, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditors reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily and was well-documented in all five establishments

13.2 Testing for Salmonella Species

No deficiencies were identified regarding the testing programs for Salmonella species.

13.3 Species Verification

At the time of this audit, Finland was required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

• Two of five establishments audited had inadequate enforcement of U.S. requirements.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within

those countries, and the importation of only eligible meat products from other counties for further processing.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on January 28, 2004, in Helsinki with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditors.

Ato Milen

The CCA understood and accepted the findings.

Dr. Oto Urban International Audit Staff Officer

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms Individual Foreign Laboratory Forms Foreign Country Response to Draft Final Audit Report U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS

REVIEW DATE

NAME OF FOREIGN LABORATORY

FOREIGN COUNTRY LABORATORY REVIEW

National Veterinary and Food Research Institute (EELA)

FOREIGN GOV'T AGENCY National Food Agency CITY & COUNTRY Helsinki, Finland

ADDRESS OF LABORATORY

Helsinki, Finland

NAME OF REVIEWER Dr. Oto Urban

NAME OF FOREIGN OFFICIAL

Ann Farerlund, NFA, Seija Berg EELA

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	Timely Analyses	03	TION C	A	A	. A	A	A	A	A	A	A	A	
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ANALYTICAL PROCEDURES	Correct Tissue(s)	08	ION CC	A	A	A	A	A	A	С	С	С	A	
ANAL. PROCE	Equipment Operation	09	EVALUATION	A	A	A	A	A	A	A	• A	A	A	
	Instrument Printouts	10	EV,	A	A	A	A	A	A	A	A	A	A	
	Minimum Detection Levels	11		A	A	A	A	A	A	A	A	A	A	
CE	Recovery Frequency	12	<u>u</u>	A	A	A	A	A	A	A	A	A	0	
URAN	Percent Recovery	13	CODE	A	A	A	A	A	A	A	С	A	A	
QUALITY ASSURANCE PROCEDURES	Check Sample Frequency	14	EVALUATION	A	A	A	A	A	A	A	A	A	A	
ALIT. PRO	All analyst w/Check Samples	15	ALU/	A	A	A	A	A	A	A	A	A	A	
σn	Corrective Actions	16		A	A	A	A	A	A	A	A	A	A	
·	International Check Samples	17		A	A	A	0	A	A	A	A	A	A	
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL, CODE	О	0	О	0	0	0	0	О	0	0	
OTHER REVIEW		19	CODE										!	
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Mangoor H. Chaudry

a/17/04

FOR	EIGN CO	UNTRY LABORATOR	Y REVIEW	- REVIEW DATE	NAME OF FOREIGN LABORATORY
	· -	(Comment Sheet)		1-22-04	National Veterinary and Food Research Institute (EELA)
FOREIGN GOV'T AGENCY National Food Agency CITY & COUNTE Helsinki, Finla					ADDRESS OF LABORATORY Helsinki, Finland
NAME OF F Dr. Oto U			NAME OF FOREIGN Ann Farerlund, N		EELA
RESIDUE	ITEM			COMM	1ENTS
Species	07	Cooked meat methodo U.S.	logy for species ve	erification testing	g was applied on raw meat samples destined to export to
501,800, 923	08	The following tissue m	atrices were used:	for DES - urine	e and feces, for sulfonamides - muscle, and for
800 j	13	Some recoveries for su sulfonamides.	lfonamides were a	as low as 50%. 1	FSIS expects a minimum of 70% recovery for
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FS.S FORM 9520-4 (9/96)

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NAME OF FOREIGN LABORATORY REVIEW DATE U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS 01-19-04 Ruokatalo Oyj, Forssan Laboratory in Forssa FOREIGN COUNTRY LABORATORY REVIEW ADDRESS OF LABORATORY CITY & COUNTRY FOREIGN GOV'T AGENCY Forssa, Finland Forssa, Finland National Food Agency NAME OF FOREIGN OFFICIAL NAME OF REVIEWER Drs. Anna-Maija Gronlund, Marjoriikka Keranen Dr. Oto Urban Residue Code/Name Ecol REVIEW ITEMS ITEM # Sample Handling 01 SAMPLING PROCEDURES Sampling Frequency 02 CODE \mathbf{A} EVALUATION Timely Analyses 03 Α Compositing Procedure 04 0 Interpret Comp Data 05 0 Data Reporting 06 \mathbf{A} Acceptable Method 07 CODE \mathbf{A} ANALYTICAL PROCEDURES Correct Tissue(s) 08 EVALUATION \mathbf{A} Equipment Operation 09 A Instrument Printouts 10 o Minimum Detection Levels 11 o QUALITY ASSURANCE Recovery Frequency 12 o Percent Recovery 13 o ALUATION Check Sample Frequency 14 \mathbf{A} All analyst w/Check Samples 15 A Corrective Actions 16 A International Check Samples 17 A PROCEDURES EVAL, CODE 18 Corrected Prior Deficiencies O CODE 20 manger H. Chardery SIGNATURE OF REVIEWER 2/17/04

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

FORSSA 5. NAME OF AUDITOR(S) 6. TYPE OF AUDIT Dr. Oto Urban V ON-SITE AUDIT DOCUMENT AU Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable. Part A - Sanitation Standard Operating Procedures (SSOP) Audit Part D - Continued Audit	1. ESTABLISHMENT NAME AND LOCATION	2. AUDITI		3. ESTA	BLISHMENT NO.	4. NAME OF COUNTRY		
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- 60. Observation of the Establishment
 - FINLAND Est.18 01-19-04
 - 13/51. Establishment pre-operational sanitation inspection records did not include descriptions of the deficiencies found. (9 CFR 416.16)
 - 19/51. Calibration, although performed, was not clearly delineated and the frequency and procedures will be reevaluated. (9 CFR 417.4)
 - 38/51/56. NFA personnel were not able to interpret the results sheets from the pest control contactor. No actual pest control problems were observed. (9 CFR 416.2a) (EC Dir. 64/433)
 - 41/56. Condensation was noted on the cooling system in the cooler. No product contamination was observed. The establishment immediately wiped the area. (9 CFR 416.2d) (EC Dir. 64/433)
 - 46/56. A large jug of liquid in the equipment cleaning room was noticed to be unlabeled. The jug was immediately removed and the contents disposed of. A roll of plastic was on a stand that allowed it to touch the floor. This was immediately removed from the area. In the blender room, plastic to be used as a packaging material was being stored in an inedible-designed container. This plastic was disposed of. (9 CFR 416.4a) (EC Dir. 64/433)

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE go mangered H - Chaudry 2/17/04

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. 5	ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3	, ESTABLISHMENT NO.	4. NAME OF COUNTRY	
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	Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		-	10. Light		
	Developed and implemented a written HACCP plan .		7_4	11. Ventilation		_
15.	Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actio	ns.	-	2. Plumbing and Sewage		
	Records documenting implementation and monitoring of the HACCP plan.		\vdash	4. December Supply	ui	
17.	The HACCP plan is signed and dated by the responsible establishment individual.		\vdash	Dressing Rooms/Lavato Equipment and Utensils		- X
	Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		4	6. Sanitary Operations		X
18.	Monitoring of HACCP plan.	,	4	7. Employee Hygiene		
19.	Verification and validation of HACCP plan.		7	8. Condemned Product Co	ntrol	
20.	Corrective action written in HACCP plan.		7	o. Obligatima (1000c) 00		
21.	Reassessed adequacy of the HACCP plan.		1	Part F - In	spection Requirements	
22.	Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurre		4	9. Government Staffing		
	Part C - Economic / Wholesomeness		50	0. Daily Inspection Coverag	ge	i
23.	Labeling - Product Standards	. 0		1 Enforcement		
24.	Labeling - Net Weights	0	Ļ	1. Enforcement		
25.	General Labeling	. 0	52	2. Humane Handling		
26.	Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moistu	ire) O	53	3. Animal Identification		į
	Part D - Sampling Generic <i>E. coli</i> Testing		54	4. Ante Mortem Inspection		
27. \	Written Procedures		55	5. Post Mortem Inspection		<u> </u>
28. 5	Sample Collection/Analysis		7			
29. F	Records	İ	7	Part G - Other Regul	atory Oversight Requirements	
Sa	ilmonella Performance Standards - Basic Requiren	nents	56	. European Community Dire	ectives	Х
30. 0	Corrective Actions		57	. Manthly Review		<u> </u>
31. F	Reassessment		58			
32. V	Nritten Assurance		59			

60. Observation of the Establishment

FINLAND - Est. 22 01-14-04

45/56 Containers designated for edible product only were used for inedible product in the deboning room (9 CFR 416.3) (EC Dir. 64/433). This deficiency was immediately corrected by the establishment management.

46/56 Overhead structures were observed with pieces of meat scraps and fat in the deboning room (9 CFR 416.4. b.) (EC Dir. 64/433). No product was directly exposed. This deficiency was corrected immediately by the establishment employee.

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

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	30. Corrective Actions		57. Mathly Review	
32. Written Assurance 59.	31. Ræssessment		58.	
	32. Written Assurance	·	59.	

60. Observation of the Establishment

FINLAND - Est. 62 01-15-04

No deficiencies observed.

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO. 4. NAME OF COUNTRY	
Koiviston Teurastamo Oy	01 - 20 - 04	85 Finland	
MELLILÄ	5. NAME OF AUDIT	OR(\$) , 5. TYPE OF AUDIT	
	Dr. Oto Urba	n X ON-SITE AUDIT DOCUM	DIT ALIDIS
Place an V in the Audit Results block to inc		pliance with requirements. Use 0 if not applicable	ENT AU'D!T
Part A - Sanitation Standard Operating Procedures (0000	Part D - Continued	
Basic Requirements	SSOP) Audit Results	· ·	Audit Results
7. Written SSOP	1	33. Scheduled Sample	
8. Records documenting implementation.	1	34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implemen	ntation. X	36. Export	!
11. Maintenance and evaluation of the effectiveness of SSOP's.	1	37. Import	
 Corrective action when the SSOPs have failed to prevent dir product contamination or aduteration. 	rect	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	X	39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	:	40. Light	
14. Developed and implemented a written HACCP plan.	į .	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective act	tions.	42. Plumbing and Sewage	
 Records documenting implementation and monitoring of the HACCP plan. 		43. Water Supply	X
 The HACCP plan is signed and dated by the responsible establishment individual. 		44. Dressing Rooms/Lavatories 45. Equipment and Utensils	<u> </u>
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations	X
18. Monitoring of HACCP plan.		47. Employee Hygiene	-
19. Verification and validation of HACCP plan.	X	48. Condemned Product Control	
20. Corrective action written in HACCP plan.	:		-
21. Reæssessed adequacy of the HACCP plan.		Part F - Inspection Requirements	Į
22. Records documenting: the written HACCP plan, monitoring of critical control points, dates and times of specific event occur		49. Government Staffing	+
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	0	51. Enforcement	
24. Labeling - Net Weights	0		<u> </u>
25. General Labeling	0	52. Humane Handling	
25. Fin. Prod. Standards/Boneiess (Defects/AQL/Pork Skins/Mois	sture) O	53. Animal Identification	
Part D - Sampling Generic <i>E. coli</i> Testing	ľ ľ	54. Ante Mortem Inspection	
27. Written Procedures		55. Post Moriem Inspection	Ţ
28. Sample Collection/Analysis	:		
29. Records		Part G - Other Regulatory Oversight Requirements	·
Salmonella Performance Standards - Basic Require	ements	56. European Community Directives	X
30. Corrective Actions		57. Mathiy Review	: <u>-</u>
31. Reassessment		58	X
32. Written Assurance	·	59.	

- 60. Observation of the Establishment
 - FINLAND Est. 85 01-20-04
 - 10/51. Fat and meat particles were observed on white tubs ready for production use. These were also re-cleaned and reinspected before use. (9 CFR 416.13)
 - 10. During operations, a hook with both grease and remnants of previous days' production was used to hoist a carcass leg to re-hang the carcass. This contacted the carcass and required additional trimming. This hook was cleaned before further use. We were told that this type of equipment would be added to the specifics for cleaning in the written SSOP. An establishment worker, (not normally in that position), was eviscerating carcasses and sometimes allowing the product to touch the floor of the stand he was working on. This product was condemned by the inspection service veterinarian. (9 CFR 415.15)
 - 46/51 Fat particles were observed on over-head structures during the pre-operational sanitation inspection in the slaughter house. The overheads were re-cleaned and inspected before production began.
 - 13/51. Establishment pre-operational sanitation inspection records did not include descriptions of the deficiencies found nor did they include complete corrective actions to include preventive measures. The descriptions presented were insufficient and included such notes as "old dirt" and "splatter". (9 CRF 416.16)
 - 19/51. Although all aspects of verification were present in both the plan documentation and implementation, there still was some confusion about calling them "monitoring" or "verification". Also, calibration, although performed, was not clearly delineated and the frequency and procedures will be reevaluated. (9 CFR 417.4)
 - 39/51/56. Excessive grease was observed on the rails and other overhead construction. No immediate action was taken, Additionally, a number of rusty bolts over hooks were observed. These were scheduled for correction. (9 CFR 416.2b) (EC Dir. 64/433)
 - 43/51/56. The water supply is municipal with additional tap testing submitted by the establishment. The latest water sample results were questionable as defined by the Finish inspection. There was no follow up of this sample. There was not a clear understanding of whose responsibility this follow-up was. (9 CFR 416.2g) (EC Dir. 64/433)
 - 45/56. An establishment employee allowed his steel to contact the stairs as he moved. He did not wash and sanitize this steel automatically, but did so after being told to by the inspection service veterinarian. No product contact was observed. (9 CFR 416.3) (EC Dir. 64/433)
 - 58. Based on the above observations, NFA has issued a Notice-of-Intended-Delistment to this establishment.

62. AUDITOR SIGNATURE AND DATE

61. NAME OF AUDITOR Dr. Oto Urban

mangoor H. Chaudry 2/17/04

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

2. AUDIT DATE	3. ESTABLISHMENT NO. 4. NAME OF COUNTRY	
01 - 23 - 04	6475 Finland	
5. NAME OF AUD!	TOR(S) 6. TYPE OF AUDIT	
i L. Dr. Oto Urb	van	
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	33. Scheduled Sample	. 0
	34. Species Testing	0
	35. Residue	0
ļ	Part E - Other Requirements	
ntation.	36. Export	
	37. Import	
ect	38. Establishment Grounds and Pest Control	
X	39. Establishment Construction/Maintenance	I
	40. Light	
0	41. Ventilation	
ions.	42. Plumbing and Sewage	
0	43. Water Supply	ļ
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	48. Condemned Product Control	
	Part F - Inspection Requirements	
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Terbes.	50. Daily laspaiting Coverage	
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	51. Enforcement	X
	52. Humane Handling	0
	53 Animal Identification	
,		0
	54. Ante Mortem Inspection	0
Ω	55. Post Mortem Inspection	0
<u> </u>	Part G - Other Regulatory Oversight Requirements	
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ments	56. European Community Directives	:
0	57. Manthiy Review	
0	58.	:
0	59.	:
	O1 - 23 - 04 5. NAME OF AUDI Dr. Oto Urb SSOP)	01 - 23 - 04

60. Observation of the Establishment

FINLAND - Est. 6475 01-23-04

13/51. The establishment SSOP records were frequently missing the description of deficiencies and corrective action. The establishment scheduled corrective action. (9 CFR 416.16)

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

for Mangote H. Chaudry 2/19/04

Livsmedelsverket National Food Agency

May 12, 2004

512/43/04

Sally Stratmoen
Chief, Equivalence Section
International Policy Staff
Office of Policy, Program Development and Evaluation
Food Safety and Inspection Service
U.S. Department of Agriculture
Washington D.C. 20250
USA

Dear Ms Stratmoen

Ref: Your letter, March 12, 2004

Subject: AUDIT REPORT FOR FINLAND, JANUARY 12 - 29, 2004

The National Food Agency (NFA) has the following minor comments as regards the audit report, 2004:

3 Protocol

First paragraph: the name of the private laboratory is incorrect. It should read *HK Ruokatalo Oyj, Laboratory*.

6 Main findings

6.2.1 CCA Control Systems

Third paragraph, second sentence should read: *Three* of the establishments certified for U.S.-export are located in the Province of Western Finland and *two* in the Province of Southern Finland.

6.2.2 Ultimate Control and Supervision

First paragraph, first sentence should read: The tasks of the NFA include meat inspection and control in slaughterhouses and other establishments, approval of slaughterhouses and establishments in connection with slaughterhouses, (the rest of the sentence remains unchanged).

6.3 Headquarters Audit

The sixth bullet point of the first paragraph should read:

- Label approval records (delete "such as generic labels, and animal raising claims").

Elintarvikevirasto

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firstname.lastname@nfa.fi

8 Residue and Microbiology Laboratory Audits

The name of the private laboratory should read *HK Ruokatalo Oyj, Laboratory* (instead of Ruokatalo Oyj, Forssan Laboratory).

Foreign Establishment Audit Checklist

As regards Est. No. 85, we disagree with the following findings:

39/51/56:

According to the report *no immediate action was taken* to clean the grease in the overhead rails.

The company started to clean the rails immediately but unfortunately we did not inform the auditor about the action.

43/51/56:

The report states that the latest water sample results were questionable as defined by the Finnish inspection. There was no follow up of this sample.

It seems that there has been some misunderstanding about this matter, as the NFA personnel only detected that there was an unacceptably long delay in taking a new water sample. No other problems were identified.

Yours sincerely

Osmo Mäki-Petäys

Director

Meat and Fish Hygiene Unit

Anna-Maija Grönlund

Senior Officer

Meat and Fish Hygiene Unit